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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,238	10/21/2004	Ana Chudzinski-Tavassi	4705-0105PUS1	5260

2292 7590 08/30/2007
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EXAMINER	
ALLEN, MARIANNE P	
ART UNIT	**PAPER NUMBER**
1647	

NOTIFICATION DATE	DELIVERY MODE
08/30/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/501,238	CHUDZINSKI-TAVASSI ET AL.	
	Examiner	Art Unit	
	Marianne P. Allen	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-19* is/are pending in the application.

4a) Of the above claim(s) *16,18 and 19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *16-19* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 1-15 have been cancelled. Claims 16-19 have been newly introduced. New claim 17 is stated to correspond to Group III, original claim 14.

Applicant's election with traverse of Group III, claim 17, in the reply filed on 7/9/07 is acknowledged. The traversal is on the ground(s) that the newly introduced claims do not lack unity. This is not found persuasive because the claims as originally presented did lack unity as set forth in the prior Office action. There is no provision for subsequently amending the claims to provide a special technical feature and thereby create unity of invention. Furthermore, applicant's assertion that SEQ ID NO: 3 is the special technical feature is not persuasive as claim 17 does not require SEQ ID NO: 3. Claim 17 recites "at least one of SEQ ID NOS: 1, 2, 3, 4 and 5."

The requirement is still deemed proper and is therefore made FINAL.

Claims 16 and 18-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7/9/07.

Specification

The disclosure is objected to because of the following informalities: The specification does not contain sequence identifiers for the sequences disclosed therein.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 17 is not an originally filed claim. Basis is stated to be in original claim 14 and pages 16-17. This is not agreed with. Original claim 14 required that the prothrombin activator be isolated by a particular process and that its function was as a "dysfibrinogening agent in prothrombotic state patients." Pages 16-17 disclose using the prothrombin activator as a "dysfibrinogening element in phrothrombotic states." These pages disclose using "low doses of purified protein...in controlled conditions, to withdraw fibrinogen from circulation, transforming it in fibrin microthrombs. The decrease on the concentration of the plasmatic fibrinogen promotes the increasing of the coagulation time and therefore it will refrain acute vascular thrombosis. Since protein does not present proteolytic activity, it could maintain the coagulation capacity of the fibrinogen not consumed in the process. This way the fibrinogen plasmatic concentration would decrease, however there would not be predisposition for hemorrhagic state." These disclosures do not speak to "treating prothrombotic disorders in an individual in need thereof" as recited in claim 17. These disclosures do not speak to administering "at least one

amino acid sequence selected from the group consisting of SEQ ID NOS: 1, 2, 3, 4 and 5, wherein said effective dose prevents blood clot formation" as recited in claim 17. Claim 17 differs substantially from original claim 14 and the disclosure on pages 16-17. The originally filed claims and specification do not support the invention as is now claimed.

Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 17 recites administering "at least one amino acid sequence selected from the group consisting of SEQ ID NOS: 1, 2, 3, 4 and 5, wherein said effective dose prevents blood clot formation."

Review of the sequence listing and the specification at page 15 reveals the following:

SEQ ID NO: 1 is a 46 amino acid protein corresponding to the N-terminus of the Lopap protein.

SEQ ID NO: 2 is an 11 amino acid internal fragment I of the Lopap protein.

SEQ ID NO: 3 is a 16 amino acid internal fragment II of the Lopap protein.

SEQ ID NO: 4 is a 7 amino acid internal fragment III of the Lopap protein.

SEQ ID NO: 5 is an 18 amino acid internal fragment IV of the Lopap protein.

There is no evidence of record nor reason to believe that any of these protein fragments individually or collectively have any biological activity, particularly that required by claim 17. Their size alone would lead one of ordinary skill in the art to doubt that they possessed any

biological activity. These sequences are disclosed as being about 15 % of the sequence of the whole 69 kD protein. The structure of the 69kD protein is not provided by the specification. While the whole protein was tested for biological activity, no fragments were tested.

It is further noted that no example in the specification appears to demonstrate prevention of blood clot formation. The examples show that intravenous administration to rats of the whole, purified Lopap protein resulted in thrombus (clot) formation followed by severe organ damage due to hemorrhage. See at least pages 34-38. There is no example or guidance in the specification leading one of ordinary skill in the art to administer any or all of the proteins as recited in claim 17 that would have been expected to provide the results recited in claim 17.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Reis et al. (Thrombosis Research, 102(5):427-436, June 2001, of record) discloses a prothrombin activator protein from *L. obliqua* that contains the partial sequences of SEQ ID NOS: 1, 2, 3, and 5. See abstract and page 432. This protein is disclosed as being important in consumptive coagulopathy. See page 435. Reis et al. does not disclose nor fairly suggest administration of this protein to prevent blood clot formation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Friday, 5:30 am - 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marianne P. Allen
Primary Examiner
Art Unit 1647

8/22/07

mpa